COVID-19 Update

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- Epidemiology
- Variants

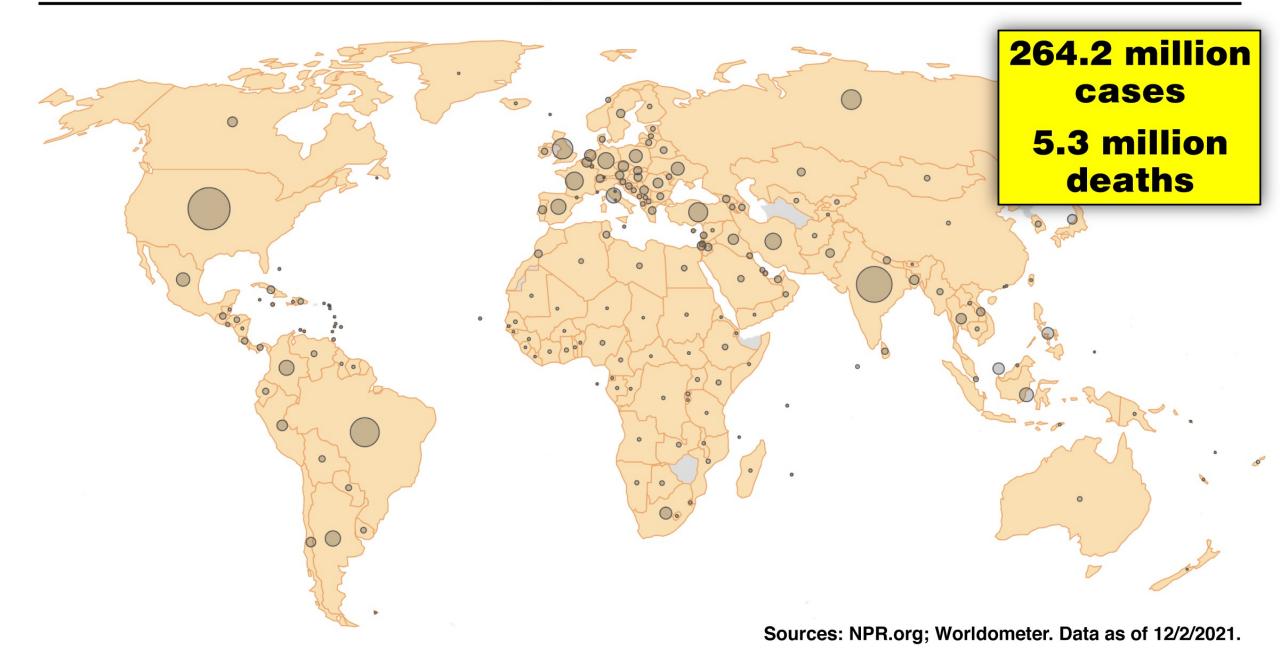
- Therapeutics
 - Pediatric Vaccines

Booster Shots

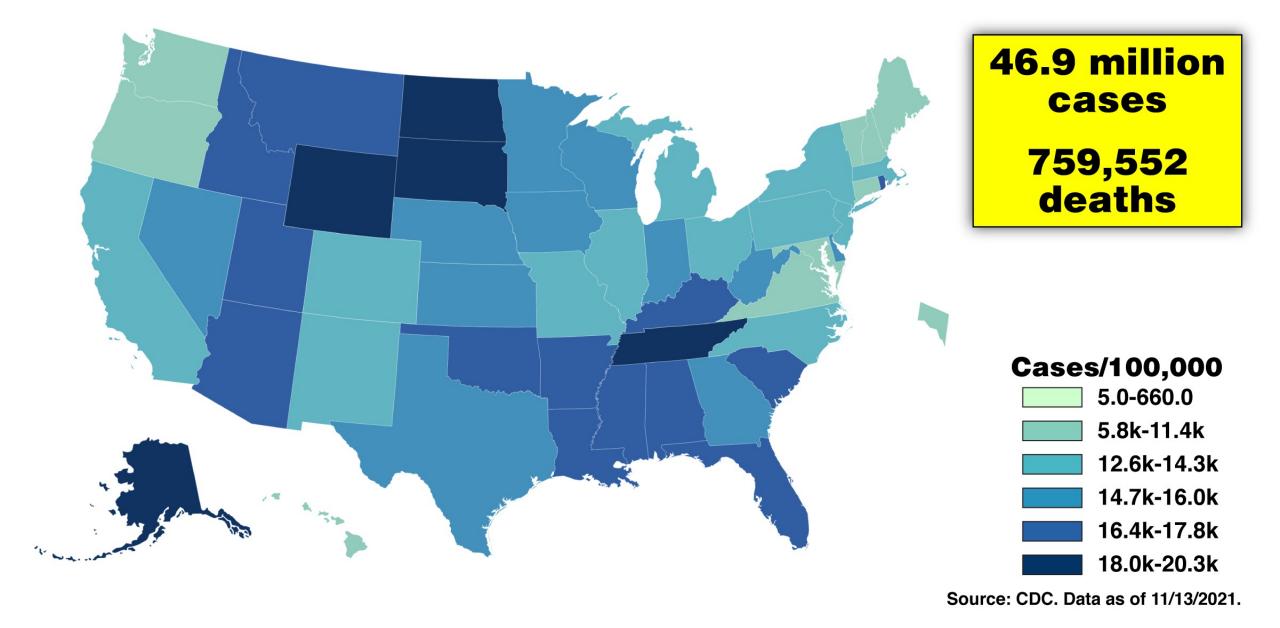
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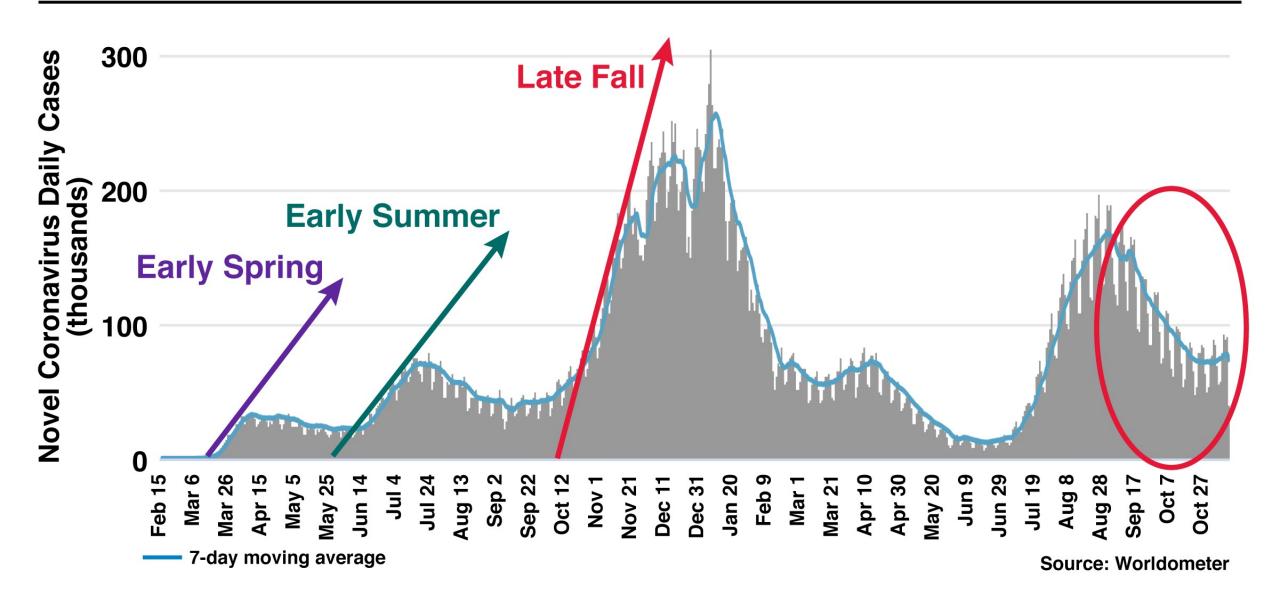
COVID-19 Globally



COVID-19 in the United States



Daily New COVID-19 Cases Reported in the United States



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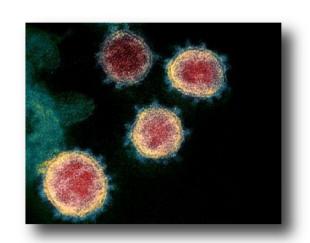
WHO SARS-CoV-2 Variants of Concern (VOCs)

WHO name	PANGO lineage*	Earliest documented samples
Alpha	B.1.1.7	9/2020
Beta	B.1.351	5/2020
Gamma	P.1	11/2020
Delta	B.1.617.2	10/2020
Omicron	B.1.1.529	11/2021

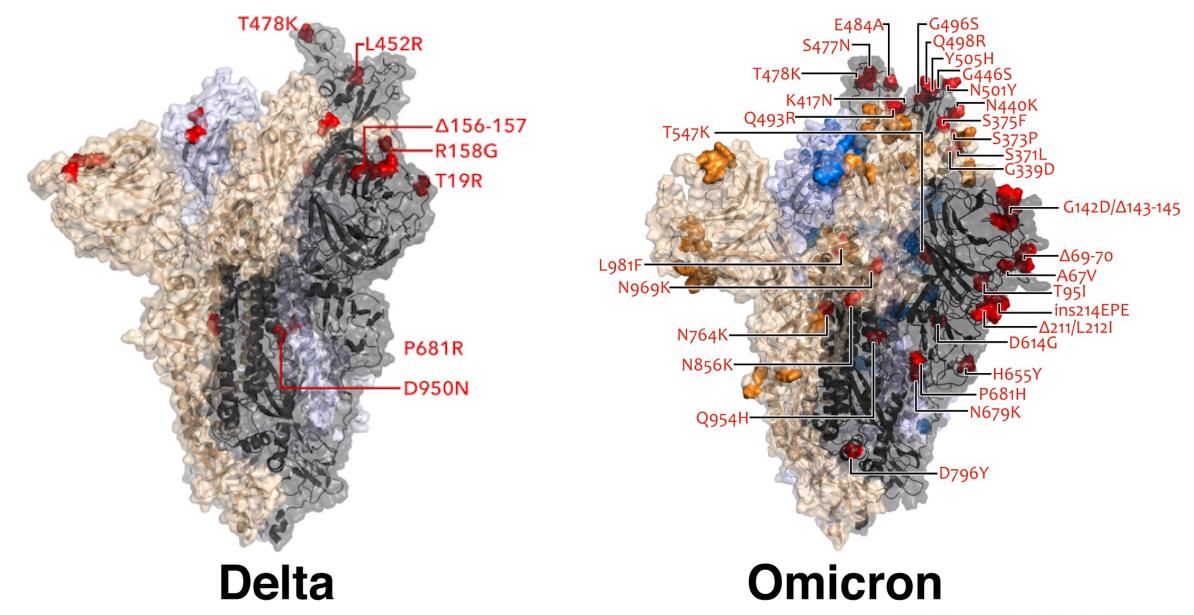
^{*}VOCs also include descendent lineages

SARS-CoV-2 B.1.1.529 (Omicron) Variant

- Novel variant first reported in Botswana (11/11) and South Africa (11/14)
- Larger number of mutations (~50) than previous variants, some anticipated to impact transmissibility and antibody binding
- Variant cases rapidly increased in Gauteng province, South Africa, and present in all other S.A. provinces
- Confirmed cases (371) now reported from 24 countries (1 in United States)
- Called 'Omicron' by WHO and named the fifth SARS-CoV-2 variant of concern on 11/26/2021



SARS-CoV-2 Spike Protein Mutations



Source: http://sars2.cvr.gla.ac.uk/cog-uk/

Potential Properties of Omicron*

- Transmission
 - May have increased transmission compared to the original pandemic virus
 - Difficult to infer if more transmissible than Delta
- Vaccine effectiveness
 - Significant reductions in neutralizing titer possible
 - As with other variants, partial immune escape may occur, but vaccines likely will still protect against severe disease
- Disease severity
 - Severity estimates are difficult given small number of cases
 - Preliminary information from South Africa suggests no unusual symptoms associated with variant

^{*}Based on Data for Other Variants with Similar Mutations

For Immediate Release

Wednesday, December 1, 2021

First Confirmed Case of Omicron Variant Detected in the United States

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Booster Shots

Molnupiravir: Clinical Data Released Nov. 26, 2021 by Merck and Ridgeback Biotherapeutics

- Placebo-controlled trial; n =1,433
- Endpoint: prevention of hospitalization or death
- 30% decrease in hospitalization/death in treatment arm; 9 deaths in placebo arm, 1 death in treatment arm
- FDA Advisory committee voted to approve drug for use in high-risk patients Nov 30, 2021



Paxlovid (Protease Inhibitor + Ritonavir): Clinical Data Announced Nov. 5, 2021 by Pfizer

- Placebo-controlled phase 2/3 trial of ~3,000 people; DSMB stopped study early at scheduled interim analysis of 1,219 people
- Subjects with a laboratory-confirmed diagnosis of SARS-CoV-2 infection with mild-to-moderate symptoms and at least one characteristic/medical condition associated with an increased risk of developing severe illness from COVID-19
- Patients randomized (1:1) to receive Paxlovid or placebo orally every 12 hours for five days.
- 89% reduction in hospitalization or death compared to placebo; 10 deaths in placebo arm, no deaths in treatment arm.
- Adverse events similar in placebo and treatment arms

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Booster Shots

CDC Newsroom

For Immediate Release

Tuesday, November 2, 2021

CDC Recommends Pediatric COVID-19 Vaccine for Children 5 to 11 Years

Today, CDC Director Rochelle P. Walensky, M.D., M.P.H., endorsed the CDC Advisory Committee on Immunization Practices' (ACIP) recommendation that children 5 to 11 years old be vaccinated against COVID-19 with the Pfizer-BioNTech pediatric vaccine.

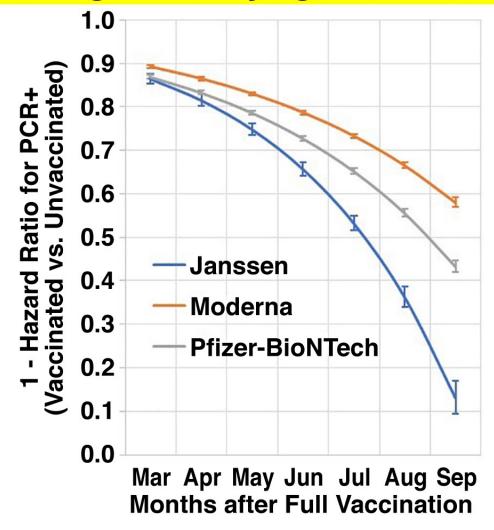
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Booster Shots

Waning Immunity after COVID-19 Vaccination Among U.S. Veterans, 2021

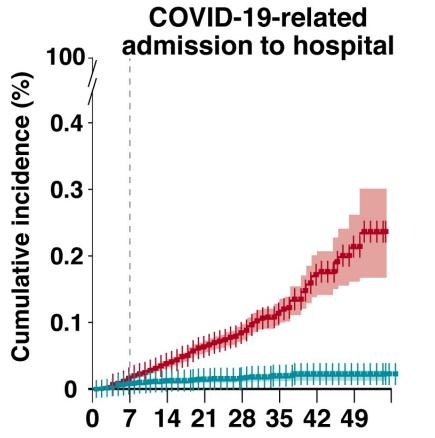
Waning immunity against infection

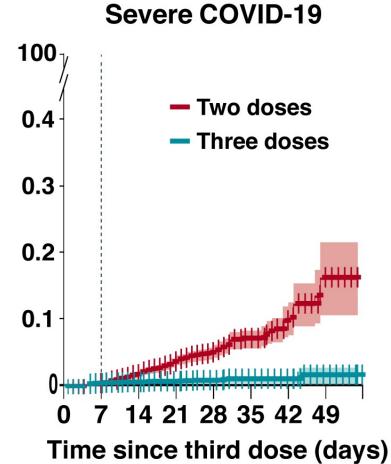


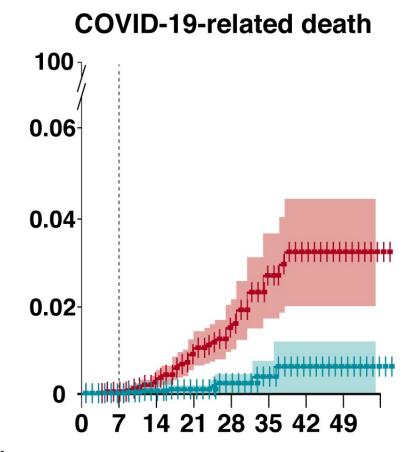
- Vaccine effectiveness (VE) against SARS-CoV-2 infection declined from 87.9% to 48.1% from Feb. to Oct., 2021
- From July to October 2021 (Delta predominant period), VE against COVID-19 death:
 - age <65 years: 73.0% for Janssen, 81.5% for Moderna, 84.3% for Pfizer-BioNTech
 - age ≥65 years: 52.2% for Janssen, 75.5% for Moderna, 70.1% for Pfizer-BioNTech

Source: BA Cohn et al. Science, 11/4/2021.

Israel: Cumulative Incidence Curves Comparing COVID-19-Related Hospital Admissions, Severe Disease and Death in People Who Received 2 Versus 3 Doses of BNT162b2 Vaccine







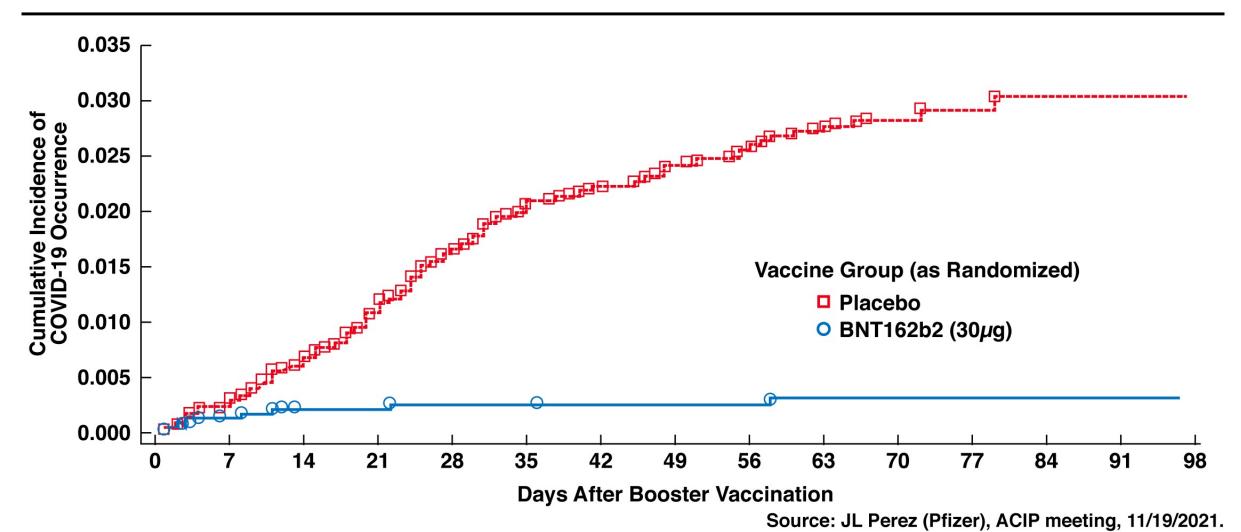
Source: N Barda et al. Lancet, 10/29/2021.

Study C4591031: Efficacy & Safety of BNT162b2 Booster

- ~10,000 participants ≥16 years of age in Brazil, South Africa and United States
- In 2-month interim analysis, efficacy against symptomatic COVID-19 in the boosted group compared to the unboosted group was 95.6%
- Efficacy was consistent irrespective of age, sex, race, ethnicity, comorbid conditions
- Adverse events were consistent with those seen in previous studies

Source: JL Perez (Pfizer), ACIP meeting, 11/19/2021.

Study C4591031: Cumulative Incidence Curve for First COVID-19 Occurrence After Booster Vaccination



Every Adult Should Get a Booster Shot



CDC Newsroom

For Immediate Release

Monday, November 29, 2021

CDC Expands COVID-19 Booster Recommendations

SARS-CoV-2 in 2022: What the Future Holds



